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REMARKS

Applicants acknowledge the Examiner's determination that claims 20, 21 and 23-25 contain allowable subject matter. Claim 19 has been amended to incorporate the limitation of claim 20 and claim 20 has been cancelled. Claim 21 has been placed in independent form incorporating all the limitations of claim 19 from which it originally depended.

Claim 35 stands rejected under 35 USC § 112, second paragraph as being indefinite. Applicants have amended claim 35 to depend from claim 33. The amendment is believed to fully address the Examiner's rejection and applicants respectfully request the withdrawal of the rejection of claim 35, as amended, for indefiniteness.

Claims 19, 22 and 38 stand rejected under 35 USC § 102 as being anticipated by Phillips (US 5556761). Claims 22 and 38 depend from claim 19, and claim 19 has been amended to incorporate the limitations of previous claim 20, thus rendering the rejection moot.

Claims 19, 22 and 38 stand rejected under 35 USC § 102 as being anticipated by Charlton (US 5520883). Claims 22 and 38 depend from claim 19, and claim 19 has been amended to incorporate the limitations of previous claim 20, thus rendering the rejection moot.

Claims 19, 22, 26-34 and 38 stand rejected under 35 USC § 102 as being anticipated by Phillips (US 5843692). Claims 22 and 38 depend from claim 19, and claim 19 has been amended to incorporate the limitations of previous claim 20, thus rendering the rejection moot as to those claims. With regards to the rejection of claims 26-34 applicants traverse the rejection of those claims.

The Philips '692 patent discloses a device and method for measuring glucose in whole blood using a reagent test strip that comprises a reagent that interacts with glucose to produce a signal that is proportional to the concentration of glucose. However, the reference is devoid of

any teaching or suggestion regarding a device that is capable of analyzing the volume of sample applied to the test element to determine whether underdosage of the test strip has occurred. More particularly, Philips '692 fails to teach a device that is capable of measuring the signal generated from two separate signal generating substances, wherein the signal generated from one substance is indicative of the amount of a target analyte and the second signal is indicative of the volume of the sample loaded. Accordingly, as noted by the Examiner in numbered paragraph 14 on page 6 of the Office Action, Philips '761 fails to teach a device that includes an electronic assembly configured to determine whether an underdosage of sample has occurred on the test element.

Claims 26-31 all specifically require the device to include an electronic assembly that operates an "optical measuring device to assess the volume of a liquid sample placed on a test element." Claims 27 and 28 further require that the claimed device must be capable of analyzing the detected signals to determine not only the concentration of the analyte in the sample but also to "assess the amount of sample placed on the test element" to determine if an underdosage of sample has occurred on the test element. Claim 29 further requires the device to be capable of correcting the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value. The device disclosed by Philips '692 provides no means for conducting such analysis with regards to underdosage of the sample.

Furthermore, Philips '692 fails to disclose the test strip as claimed in claim 32. The test strip of claim 32 specifically requires the presence of both a reagent and a control substance, wherein the reagent interacts with the target analyte to produce a signal proportional to the concentration of the analyte, and the control substance produces a signal upon contact with the

sample to produce a signal proportional to the volume loaded on the test strip. Philips '692 simply fails to teach a test strip that comprises two separate compounds wherein upon contact with a sample, one compound produces a signal indicative of target analyte concentration and the second compound produces a signal indicating whether the test strip has been loaded with a sufficient amount of sample.

Accordingly, applicants respectfully submit that Philips '692 fails to anticipate the invention of claims 26-34 due to the failure of that reference to teach a device that has means for analyzing whether or not the test strip has been underdosed. The claimed invention is novel in light of the Philips '692 teachings, and applicants respectfully request the withdrawal of the rejection of claims 19, 22, 26-34 and 38 as being anticipated by Philips '692.

Claims 35-37 stand rejected under 35 USC § 103 as being unpatentable over Philips '692 in view of Sigler (US 6140137). As noted above, the primary Philips '692 reference fails to teach or suggest a test strip that comprises two separate compounds, the first for generating a signal that is proportionate to the amount of analyte present in an sample applied to the test strip, and the second for producing a signal indicative of the volume of sample applied to the test strip. The secondary Sigler reference discloses various compounds used in applicants' claimed test strip, but fails to teach or suggest the use of fluorescein or chlorophenol red to measure the volume of a sample placed on a test strip. Nor do the cited references alone or combined for all their teachings suggest the combination of two distinct compounds on a single test strip, wherein the two compounds are used to detect underdosage of the test strip and measure analyte concentration, respectively. The motivation to combine the "reagent" and "control substance" on a single test strip comes solely from applicants' recognition that two compounds can be used in a single test strip to measure both the volume of sample added to the test strip as well as the

amount of a target analyte present in the sample. Thus the combination allows for adjustments to be made regarding the concentration of the analyte when the test strip is underdosed. The prior art fails to teach or suggest the unique combination of elements (specifically the combination of an analyte detecting reagent and a control substance) used in applicants' claimed test element that allow for the detection and compensation of an underdosage of the test strip. Accordingly, claims 35-37 are believed to be patentable over the combined teachings of the cited references.

The claims are believed to be in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance. If any further discussion of this matter would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,

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